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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
09/728,171	12/01/2000	Brent R. Constantz	CORA-007CIP 3702		
24353	7590 05/05/20		EXAMINER		
BOZICEVIC, FIELD & FRANCIS LLP 200 MIDDLEFIELD RD			KIM, JENNIFER M		
SUITE 200		ART UNIT	PAPER NUMBER		
MENLO PARK, CA 94025			1617		

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

		Applicat	ion No.	Applicant(s)			
Office Action Summary		09/728,	171	CONSTANTZ, BRENT R.			
		Examine	er	Art Unit			
		Jennifer		1617			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply							
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).							
Status							
1)🖂	1)⊠ Responsive to communication(s) filed on <u>20 April 2004</u> .						
2a) <u></u> ☐	This action is FINAL . 2b)⊠ This action is non-final.						
3)	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Dispositi	on of Claims						
 4) Claim(s) 1-5,7-12 and 14-19 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) 1-5,7-12,14-19 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement. 							
Applicati	on Papers						
9)☐ The specification is objected to by the Examiner.							
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.							
Priority u	nder 35 U.S.C. § 119						
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 							
Attachment	(s)						
	of References Cited (PTO-892)		4) Interview Summary (F				
3) 🔲 Inform	of Draftsperson's Patent Drawing Review (PTO-948 ation Disclosure Statement(s) (PTO-1449 or PTO/SE No(s)/Mail Date		Paper No(s)/Mail Date 5) Notice of Informal Pat 6) Other:				

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20, 2004 has been entered.

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DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April

Specification

The amendment filed on April 20 2004 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The phase "the catheter devices of the subject invention also typically include a means for isolating the local environment of the target lesion" lacks literal support and this phrase introduces is new matter since it introduces new invention by isolating the local environment of the target lesion not supported by the original disclosure.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 102

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-5, 7-12 and 14-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Hausheer et al. (U.S.5,902,610) of record.

Hausheer et al. teach a pharmaceutical formulation comprising a solution of an inorganic acid solution (i.e. hydrochloric acid) and a salt (i.e. NaCl), with pH range of 2 to 6, suitable for parenteral administration (i.e. intraperitoneal, subcutaneous, intraarterial, intravenous) by mean administration by hypodermic needle or **catheter**.

Applicant's recitation in claims 1, 8 and 15 of an intended use of catheter for dynamically introducing the solution and aspirating the solution does not represent a patentable limitation since such fails to impart any physical limitation to the composition in the prior and there is no reason why the same "catheter" utilized by the prior is not capable of performing the intended use since the "kit" claimed by the Applicant

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comprises same solution having a same subphysiologic pH and a fluid delivery device, i.e. catheter. The "kit" to be employed would be inherent upon administration of the composition (hydrochloric acid and a salt) with the catheter as taught by Hausheer et al.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited reference. The claims are therefore properly rejected under 35 U.S.C. 102(e).

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sreenivasan Padmanabhan Supervisory Examiner Art Unit 1617

Jmk April 28, 2004